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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/954,954 10/21/97 SUMMERS N 2991/1

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EXAMINER

KEMMERER, E

ART UNIT

PAPER NUMBER

1646

21

DATE MAILED:

11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/954,954

Applicant

Summers et al.

Examiner
Elizabeth C. Kemmerer

Group Art Unit
1646



☒ Responsive to communication(s) filed on 19 Sep 2000

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) 15-22 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-14 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-22 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Status of Application, Amendments, And/Or Claims

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on has been entered.

The amendment filed 19 September 2000 (Paper No. 14) has been entered in full. Claims 15-22 remain withdrawn from consideration as being directed to a non-elected invention. Claims 1-14 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection of claims 4, 9 and 11-14 under 35 U.S.C. § 112, second paragraph, as set forth at pp. 2-3 of the previous Office Action (Paper No. 13, 14 October 1999) is *withdrawn* in view of amended claim 4 (Paper No. 20, 19 September 2000).

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35 U.S.C. § 103

Claims 1, 5 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pastan et al. in view of Lin. The basis for this rejection is of record (e.g., pp. 3-8 of Paper No. 9, 29 April 1999).

Applicant's arguments (pp. 3-5, Paper No. 20, 19 September 2000) have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant characterizes Pastan et al. as providing only general statements that circular permutation can be applied to other ligands, and provide only general guidance to the selection of opening sites. Applicant indicates that such is not sufficient to provide a *prima facie* case of obviousness. This is not found to be persuasive because Lin provides detailed information regarding conserved sequences of EPO. Pastan et al. is relied upon as a secondary reference for suggesting circular permutation of EPO which retains its activity in the context of a fusion protein. Since Pastan et al. suggests fusion proteins comprising active circular permuteins of EPO, and Lin gives more specific structural information regarding conserved EPO sequences which will aid in the selection of an opening site, the claimed invention as a whole remains clearly *prima facie* obvious over the combined teachings of the prior art.

Applicant then quotes from a paper officially of record in the Pastan et al. patent's file. Applicant urges that these quotes reflect Pastan et al.'s belief that circular permutation is unpredictable and thus there cannot be a reasonable expectation of success in the rejection of record in this application. This is not found to be persuasive. Applicant is again reminded that the

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prosecution history of the Pastan et al. patent will not be reviewed on this record. Furthermore, whatever may have been the opinion of Pastan et al.'s representatives regarding the state of the art at the time of Pastan et al.'s invention has no bearing on the state of the art at the time of the instant bearing. The Pastan et al. patent is a pioneering patent, greatly advancing this art by its issuance. Since Pastan et al. is prior art regarding the instant invention, the state of the art is quite different when considered for this invention than it was at the time of Pastan et al.'s invention.

Finally, Applicant concludes that the combined teachings of the references do not suggest that presently claimed invention, that there is no reasonable expectation of success, and that a legally insufficient "obvious to try" standard has been applied in the instant rejection. This is not found to be persuasive. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the circularly permuted growth factors, DNA encoding same, methods of recombinantly producing same, and pharmaceutical compositions comprising same as taught by Pastan et al., and to modify that teaching by extending it to EPO disclosed by Lin, with opening sites at 25, 27, 30, 32, 80, 82, 88, 116, or 121. A reasonable expectation of success is given by Pastan et al.'s disclosure that preferred opening sites are those which can tolerate amino acid substitution and Lin's disclosure of substitution toleration at positions 25, 27, 30, 32, 80, 82, 88, 116, and 121. The motivation to do so is provided by Pastan et al. in their express suggestion to extend the teachings to EPO. Thus, the claimed invention as a whole was very clearly *prima facie* obvious over the prior art.

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Claims 1-4 and 6-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Pastan et al. in view of Lin and further in view of Chaudhary et al. and Cousens et al. The basis for this rejection is of record (e.g., pp. 8-9 of Paper No. 9, 29 April 1999).

Applicant's arguments have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant argues (pp. 5-6, Paper No. 20, 19 September 2000) that Chaudhary et al. and Cousens et al. do not remedy the alleged deficiencies of Pastan et al. and Lin for the same reasons argued in the rebuttal of the preceding rejection. These arguments have been fully considered but are not deemed to be persuasive for the reasons given above.

Conclusion

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 15-22 drawn to an invention nonelected with traverse in Paper No. 4. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ECK

November 6, 2000

ELIZABETH KEMMERER
PRIMARY EXAMINER